

Kline, Cliff

From: Michael, Maher
Sent: Monday, November 29, 2004 11:39 AM
To: 'Dawisha, Sahar'
Cc: Allen, Samie Niver; Kline, Cliff; Free, Donna
Subject: RE: response to Tables 13.1 and 13.3.1

Dear Dr. Dawisha

Please, find attached our response to your questions of November 24th, 2004. If you have any additional questions, please let us know.

Thanks

Mack

-----Original Message-----

From: Dawisha, Sahar [mailto:SXD@CDRH.FDA.GOV]
Sent: Wednesday, November 24, 2004 12:19 PM
To: 'Free, Donna'; Dawisha, Sahar
Cc: Allen, Samie Niver; Michael, Maher; Kline, Cliff
Subject: RE: response to Tables 13.1 and 13.3.1

Thanks Donna,

Could you provide the number of implants associated with the attachment?

Also, could you clarify the number of implants pertaining to each patient # shown in Table 5 4 13 1-C in Attachment 18?

Thanks.
Sahar

-----Original Message-----

From: Free, Donna [mailto:DFree@mentorcorp.com]
Sent: Friday, November 19, 2004 1:14 PM
To: 'Dawisha, Sahar'
Cc: 'Allen, Samie Niver'; Michael, Maher; Kline, Cliff
Subject: response to Tables 13.1 and 13.3.1

Hi Sahar,

Attached please find our response to your questions regarding MRI accounting tables 13.1 and 13.3.1. Please let us know if you require additional information.

Thanks and have a nice weekend

Donna

12/20/2004

2005 APR 6 1 11 PM

1. Could you provide the number of implants associated with the attachment?

1 Response:

There were 21 implants associated with the attachment. Below is a table listing the number of implants for patients that had MRI scans after explant of their original Core Gel Implants

Patient	Number of Implants
	2
	2
	1
	2
	1
	1
	1
	1
	2
	2
	2
	2
	2
	2
Total	21

2. Also, could you clarify the number of implants pertaining to each patient # shown in Table 5.4.13.1-C in Attachment 18?

2 Response:

The number of implants pertaining to each patient in Table 5.4.13.1-C was provided in Table 5.4.13.1-B in the column entitled "Implants" in Attachment 18. It is reproduced below, with the additional column of "Breast Side."

Table 5.4.13.1-B: Number of Device Considered

To be ruptured

Subject	Indication	Patients	Implants	Breast Side
	Revision	1	2	L, R
	Augmentation	1	1	R
	Revision	1	2	L, R
	Revision	1	1	L
	Reconstruction	1	1	L
	Revision	1	1	L
	Total	6	8	-